

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addiese: COMMISSIONER FOR PATENTS P O Box 1450 Alexandra, Virginia 22313-1450 www.wepto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|---------------------------|----------------------|----------------------|------------------|
| 10/552,390 | 05/30/2006 | Neil Russell Foster | MAP1130 | 4759 |
| 28213 DLA PIPER L | 7590 02/15/201 LP (US) | 1 | EXAM | INER |
| 4365 EXECUTIVE DRIVE | | | ZALASKY, KATHERINE M | |
| SUITE 1100 SAN DIEGO. | CA 92121-2133 | | ART UNIT | PAPER NUMBER |
| , | | | 1777 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/15/2011 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

| Application No. | Applicant(s) | | | |
|-------------------|---------------|--|--|--|
| | | | | |
| 10/552,390 | FOSTER ET AL. | | | |
| | | | | |
| Examiner | Art Unit | | | |
| KATHERINE ZALASKY | 1777 | | | |

The MAILING DATE of this communication appears on the cover sheet with the correspondence address

| ominou | patient term | aujuoimoni. | 056 07 | 011111.7 | 041 |
|--------|--------------|-------------|--------|----------|-----|
| | | | | | |
| | | | | | |

| Period for F | Reply |
|--|--|
| WHICHI - Extension after SIX - If NO pe - Failure to Any reply | RTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, EVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. In a of time may be available under the provisions of 37 OFF 1.136(3). In no event, however, may a reply be timely lifed (16) MONTHS from the mailing date of this communication. (6) MONTHS from the mailing date of this communication of reply a specified above, the renormal station by pack will apply and will expise SIX (6) MONTHS from the mailing date of this communication of reply a specified above, the renormal station by a control of the specified above, the renormal station of the specified above |
| Status | |
| 1)⊠ Re | esponsive to communication(s) filed on 22 October 2010. |
| 2a) 🔲 Th | nis action is FINAL . 2b) This action is non-final. |
| | ince this application is in condition for allowance except for formal matters, prosecution as to the merits is osed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. |
| Disposition | of Claims |
| 4a 5)□ Cl 6)☑ Cl 7)□ Cl | taim(s) 1-7.10-12.26.27 and 29-31 is/are pending in the application.) Of the above claim(s) is/are withdrawn from consideration. alim(s) is/are allowed. alim(s) 1-7.10-12.26.27 and 29-31 is/are rejected. alim(s) is/are objected to. alim(s) are subject to restriction and/or election requirement. |
| Application | Papers |
| 10)□ Th Ap Re | e specification is objected to by the Examiner. e drawing(s) filed on is/are: a _ accepted or b) _ objected to by the Examiner. splicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). splacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). e oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. |
| Priority und | der 35 U.S.C. § 119 |
| a) 1. 2. 3. | knowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). All b) Some colonic None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). the attached detailed Office action for a list of the certified copies not received. |
| Attachment(s) | A Determinant Clim (PTO 992) |

| 1) Notice of References Cited (PTO-892) | 4) Interview Summary (PTO-413) | |
|---|---|--|
| 2) Notice of Draftsperson's Patent Drawing Review (PTO 948) | Paper No(s)/Mall Date | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) | Notice of Informal Patent Application | |
| Paper No(s)/Mail Date 20101022. | 6) Other: | |

Application/Control Number: 10/552,390 Page 2

Art Unit: 1777

DETAILED ACTION

Claim Status

 Claims 1-7, 10-12, 26-27, and 29-31, as amended 22 October 2010, are currently pending. Claims 8-9, 13-25, and 28 are cancelled.

Claim Interpretation

- 2. It is noted that claims 1-7, 10-12, 27, and 29-31 are directed to an apparatus. Regarding limitations recited in these claims which are directed to a manner of operating disclosed apparatus, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."
- 3. Moreover, statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art apparatus (or process). See, e.g., In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962).

Claim Rejections - 35 USC § 112

Application/Control Number: 10/552,390

Art Unit: 1777

 Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites the limitation "the pressure vessel" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

- The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- Claims 1-7, 11, 27, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Mertens (DE 19714790, citations from machine translation).

Regarding claim 1, Mertens discloses an apparatus comprising:

an outer chamber for containing a dense gas, wherein the outer chamber is an autoclave (Figure 2, autoclave 10, container 11);

an inlet for supplying dense gas as a solvent (inlet 23, inlet nozzle 19, inlet nozzle 21);

a porous chamber within the outer chamber for containing a substance for dissolution or suspension with the solvent, the porous chamber having a wall which allows passage of solvent and the substance dissolved or suspended in the solvent (filter 1), and

an outlet for removing solvent and solution and/or dispersion from the outer chamber (exhaust 25, overflow pipe 24) and a turbulence means for creating turbulence within the porous chamber, wherein the turbulence creating means comprises a drive means to rotate the porous chamber within the outer chamber (turntable 13, stepping drive 14, 15).

Application/Control Number: 10/552,390

Art Unit: 1777

Regarding claim 2, Mertens discloses the apparatus wherein the inlet in the outer chamber supplies solvent directly to a mouth communicating with the porous chamber (air nozzle 19).

Regarding claim 3, Mertens discloses the apparatus wherein the inlet is in the wall of the outer chamber (inlet 23).

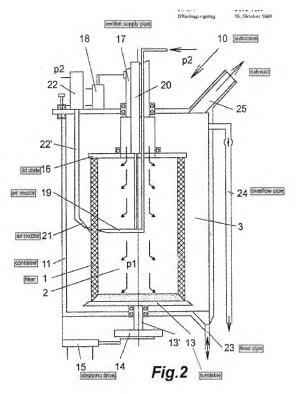
Regarding claim 4, Mertens discloses the apparatus wherein the inlet supplies solvent to the porous chamber and the region between the porous chamber and the outer chamber (air nozzle 21).

Regarding claim 5, Mertens discloses the apparatus wherein the porous chamber is further provided with a longitudinally extending shaft communicating with the solvent inlet of the porous chamber (air nozzle 19, shaft extending into the porous chamber with inlet opening at end).

Regarding claim 6, Mertens discloses the apparatus wherein the shaft is porous or perforated (air nozzle 19, shaft extending into the porous chamber with inlet opening at end, thus it is porous).

Regarding claim 7, Mertens discloses the apparatus wherein the porous chamber is adapted to receive the substance in the region around the longitudinally extending shaft and the porous chamber is adapted to receive solvent through the shaft (Figure 2, air nozzle 21, air nozzle 19, inlet 23).

Regarding claim 11, Mertens discloses the apparatus wherein the porous chamber is provided with a plug to hold the substance against the base of the inner chamber (Figure 2, lower end of filter unit is solid).



Page 6

7. Regarding limitations recited in claims 27, 29, and 30 which are directed to a manner of operating disclosed autoclave, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

Claim Rejections - 35 USC § 103

- The text of those sections of Title 35, U.S. Code not included in this action can be found
 in a prior Office action.
- 9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mertens (DE 19714790), as applied to claims 1 and 11 above, and further in view of Pesiri et al. (US 6,916,389, "Pesiri").

Regarding claim 12, Mertens discloses all of the claim limitations as set forth above.

While the reference does disclose that the plug is a planar element abutting the sides of the inner chamber (Figure 2, lower end of filter element, on turntable 13), the reference does not disclose that the plus is held against the substance by a resilient biasing means.

Pesiri discloses a pressure vessel with an inner filter (Figure 2, 102, 105, 106). The reference teaches that a spring loaded bottom plate can be used with the filter element in order to secure and seal the filter (C8/L43-46).

It would have been obvious to one having ordinary skill in the art to substitute a spring loaded bottom plate on the filter of Mertens, as taught by Pesiri, since doing so will secure the filter onto the turntable with additional pressure and will seal the bottom edge of the filter element.

Claims 1-4 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Compton (US 4.443.321) in view of Cham (US 5.744.038).

Regarding claims 1 and 31, Compton discloses an apparatus for dissolving or suspending a substance in a solvent (abstract) comprising:

- an outer chamber, wherein the outer chamber is a an autoclave (Figure 2, C4/L17-38, autoclave reactor 30)
- an inlet (Figure 2, inlet 36, C4/L17-38)
- a porous chamber within the outer chamber, the porous chamber having a wall
 which allows passage of solvent and the substance dissolved or suspended in the
 solvent (Figure 2, porous container 42, C4/L17-38)
- an outlet for removing solvent and solution and/or dispersion from the outer chamber (Figure 2, C4/L17-38, outlet leading into valve 53)

While Compton discloses that the apparatus has turbulence means for creating turbulence within the porous chamber (Figure 2, C4/L17-38), the reference does not disclose that the turbulence means comprises a drive means to rotate the porous chamber within the outer chamber. Rather, the reference suggests a drive means with a propeller-type stirrer (propeller blades 44, motor 46). The stirrer works to mix the fluids in the pressurized chamber (C4/L17-38).

Application/Control Number: 10/552,390

Art Unit: 1777

Cham is related to a pressure vessel with an internal porous chamber which is used in extraction procedures. Cham discloses that that the drive means act to rotate the inner porous chamber, as opposed to a stirring device (Figure 2, 46, C3/L26-40). Cham discloses that this type of dispersing means for the incoming fluid offers advantages over other forms of extraction and helps to produce fine droplets of the incoming fluid (C3/L26-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute the propeller-type stirrer and drive means of Compton et al. with a driven means which attaches to and rotates the inner porous chamber, as taught by Cham, since doing so provides an advantage over other forms of extraction dispersing procedures. Additionally, finer droplets of fluids will be produce so that the extraction will be more efficient.

Regarding claim 2, Compton discloses the apparatus wherein the inlet in the outer chamber supplies solvent directly to a mouth communicating with the porous chamber (Figure 2, inlet 36, C4/L17-38).

Regarding claim 3, Compton discloses the apparatus wherein the inlet is in the wall of the outer chamber (Figure 2, inlet 36, C4/L17-38).

Regarding claim 4, Compton discloses the apparatus wherein the inlet supplies solvent to the porous chamber and the region between the porous chamber and the outer chamber (Figure 2, C4/L17-38, inlet 36).

Regarding claims 5-7, 26 and 31, Compton does not disclose the apparatus wherein the porous chamber is further provided with a longitudinally extending shaft communicating with the solvent inlet of the porous chamber, or that the shaft is porous or perforated. Finally, Compton does not disclose that the porous chamber is adapted to receive the substrate in the

region around this shaft and the porous chamber is adapted to receive solvent through the shaft.

Rather, the reference suggests that the inlet tubing terminate at the container wall (inlet 36, Fig. 2).

Cham discloses an alternative arrangement of the inlet tubing, wherein a shaft with an opening at the end extends into the porous chamber for the delivery of solvents (tube 42, opening 45). Since the instant specification is silent to unexpected result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the inlet of Compton on a shaft extending into the porous chamber, as taught by Cham, because selecting one of known designs for an opening would have been considered obvious to one of ordinary skill in the art at the time of the invention and because said an opening which delivers solvent to the porous chamber would operate equally well as the one disclosed by Compton. Moreover, Cham discloses that the supply of the fluid through an inlet in the porous chamber may help to disperse the fluid into the outer chamber as the porous chamber rotates (C3/L26-39). This would be particularly useful where the apparatus is being used for delipidating plasma, which may be combined with blood and reintroduced to a subject (C3/L26-39, abstract). Therefore, one of ordinary skill in the art would be motivated to change the arrangement of the inlet opening, such that it is in the form of a shaft extending into the porous chamber, so that the fluid entering can better disperse into the surrounding fluid. This increases the utility of the device by allowing it to be appropriate for delipidation of plasma which can be later be reintroduced to a subject.

While the inlet (44) is in the form of a longitudinally extending shaft in fluid communication with the inlet (Figure 2), the reference does not disclose that the shaft is porous Application/Control Number: 10/552.390

Art Unit: 1777

along the length of the shaft. Rather, the inlet tube appears to have just a single opening on the end of the tube.

However, inlet tubes which are porous along the length, as opposed to a single opening on the end, are widely used and well known in the art (as evidenced by Green, US 4,476,928, Figures 1 & 2; Pevere et al., US 2,595,979; and McMurphy, US 5,055,185). It would have been obvious to one having ordinary skill in the art at the time of the invention to try using an inlet tube which is perforated along its length as opposed to an inlet tube which has only a single opening on the end since doing so amounts to nothing more than the choice from a finite number of predictable types of inlet tubes, all of which will perform the desired function of adding fluid to the chamber.

Regarding claims 27 and 29-30, Compton discloses that the reactor is an autoclave (C4/L17-38) which may operate at pressures between 500-5000 psig (approx. 34-344 bar) and at a wide range of temperatures (C3/L40-53). Therefore, the apparatus is capable of the functional language recited in claims 27 and 29-30.

Claim Rejections - 35 USC § 103

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Compton (US 4,443,321) and Cham (US 5,744,038), as applied to claim 1 above, and further in view of Osdor (US 3,734,160), Garrett et al. (US 4,452,701), Cole (US 6,000,625), and Ohno (US 2003/0151176).

Regarding claim 10, Compton discloses all of the claim limitations as set forth above.

While the reference is concerned with the dissolution of a solid material in a solvent, using turbulence-generating means (C4/L16-38, C5/L40-50), the reference only using a propeller-type

mixer. Particularly, the reference does not disclose the apparatus where the turbulence creating means further comprise baffles extending from the inner surface of the outer chamber in the region between the porous chamber and the wall of the outer chamber.

Osdor teaches that baffle plates are known to increase turbulence, thus providing additional mixing and dispersal of fluids (C5/L9-13). Garrett et al. teaches that an increase in turbulence is known to increase the rate of dissolution (C2/L6-9). Cole also teaches that if it is noted that there is not enough turbulence in a mixing system that additional baffles should be added to the system (C3/L13-19). Finally, Ohno et al. teaches that baffles on the inner surface of an outer chamber will aid in generating turbulence, which in turn speeds dissolution rates ([0046]).

It would have been obvious to one having ordinary skill in the art at the time of the invention to add baffles to the inner surface of the outer chamber of Compton, as taught by Osdor, Garrett et al., Cole and Ohno et al., since doing so will increase turbulence in the vessel, thereby increasing the rate of dissolution and overall, decreasing the process times.

Response to Arguments

Response to Arguments

 Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the
 examiner should be directed to KATHERINE ZALASKY whose telephone number is (571) 270-7064. The examiner can normally be reached on 7:30am - 4:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/ Primary Examiner, Art Unit 1777

/K. Z./ Examiner, Art Unit 1777 11 February 2011